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January 27, 2020

## **VIA E-MAIL**

Special Master David Cohen U.S. District Court for the Northern District of Ohio Carl B. Stokes U.S. Courthouse 801 West Superior Avenue Cleveland, Ohio 44113

RE: In Re National Prescription Opiate Litigation
U.S. District Court for the Northern District of Ohio
Case No. 1:17-md-2804

Dear Special Master Cohen:

On behalf of Plaintiffs in the CT1B cases, we write in response to your request during the January 23, 2020 teleconference for the parties to submit authority regarding the scope of certain "red flag" drug combinations.

As laid out below, authority from as far back as 1994 demonstrates that such "red flags" of diversion may include various combinations, or "cocktails," of either two, three, or four different drugs, which may be prescribed *or* presented for filling as many as 45 days apart from each other. Some of the key authorities – as well as select documents produced by Walgreens, Walmart, and Rite Aid – are summarized below. As noted in the documents cited below, some of these drug combinations have been given slang nicknames, like the "fours and doors," a two drug combination consisting of a sleep aid along with a narcotic, the "holy trinity" or "triple," a three drug combination which includes at least 1 opioid, a benzodiazepine, and carisoprodol, and the "homerun," which combines four controlled substances.

In addition to the examples cited below, a spreadsheet with over <u>fifty</u> citations to case law, administrative decisions, Defendants' own document productions, and publicly available documents is attached to this letter.

1. <u>2-Drug Combination</u>: *United States v. Veal*, 23 F.3d 985, 987 (6th Cir. 1994):

In October of 1990 investigators from the United States Drug Enforcement Administration received reports from drug wholesalers that the defendant, Dennis Veal, was making inordinately large purchases of Doriden and Tylenol 4. Doriden, a sleeping medication, and Tylenol 4, a pain medication containing codeine [an opioid pain reliever, similar to morphine], are Schedule III controlled substances.

These drugs have a heroin-like effect when ingested in combination. The combination is commonly referred to in the illegal drug market as "fours and doors." Although a registered pharmacist pays anywhere from four to seven cents per pill of either variety, a single dose of the "fours and doors" combination costs about \$20 on the street.<sup>1</sup>

2. <u>2-Drug Combination</u>: *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos.* 219 and 5195; Decision and Order, Fed. Reg. Vol. 77, No. 198, at fn. 102 (2012):

The Respondents contend that the oxycodone alprazolam combination was not a red flag in 2010, when most of the allegedly wrongful dispensing occurred. [citation omitted]. Contrary to this contention, DI Langston testified that the combination of oxycodone and Xanax (the brand name for alprazolam) was a red flag of diversion for at least "[a] couple of years ago." Tr. 90.

3. <u>2-Drug Combination</u>: 2012 Orders to Show Cause issued to Walgreens (WAGMDL00387708):

[Walgreens pharmacy filled prescriptions for] individuals presenting prescriptions for combinations of controlled substances known to be highly abused, such as oxycodone and benzodiazepines

. . .

[Walgreens pharmacy] filled eleven prescriptions for oxycodone and alprazolam cocktails.

4. <u>3-Drug Combination</u>: Walmart's policy, POM 1311 Practice Compliance Corresponding Responsibility – Proper Prescriber Patient Relationship (WMT\_MDL\_000042987), outlines prescription red flags stating:

Prescriptions presented represent a "cocktail" of commonly abused drugs or are presented in a combination that can cause medical

<sup>&</sup>lt;sup>1</sup> Tylenol 4 is a combination of the opioid pain reliever codeine and acetaminophen. With 60 mg of codeine, Tylenol 4 contains the highest dose of codeine among the various forms of Tylenol with codeine. In fact, Tylenol 4 contains twice the codeine as the next highest concentration of Tylenol with codeine, Tylenol 3, which has 30 mg of codeine.

complications. (i.e. an opioid, a benzodiazepine, and a muscle relaxant). This is often referred to as the "trinity" or "holy trinity."

5. <u>3-Drug or 4-Drug Combinations</u>: East Main Street Pharmacy, DEA Affirmance of Suspension Order, Fed. Reg. Vol. 75, No. 207, at 66158 (2010):

In his testimony, Dr. Sullivan explained that pharmacists refer to the combination of "the benzodiazepine, the narcotic pain killer, and the sleeping pill" as "[t]he triple," and that when Soma (carisoprodol) is added, the combination is known as the "homerun." Tr. 956. Noting that Volkman was issuing duplicate prescriptions for schedule II narcotics, Dr. Sullivan testified that he had never seen two schedule II narcotics prescribed together other than for treatment of cancer or hospice patients. *Id.* at 956-57, 1027-28. [footnote omitted]. He further observed that "41 of the 55 [patients] (75%) received two narcotic pain killers on the same day," and that this happened "68 different times for these 41 patients." GX 20, at 3. He then reiterated that "[t]o have two schedule II controlled substances, or two narcotics, a schedule II, and a schedule III like a Vicodin or a Lortab combined together was something [he] had never seen to this extent before these prescriptions." *Id.* at 957.

 Multiple Drug Combination: Rite Aid's manual outlining the procedure for the validation and dispensing of high alert controlled substances, NexGen Automated Red Flag Documentation Process for High Alert Controlled Substances (Rite\_Aid\_OMDL\_0044351), provides the following

Look for "Red Flags" that MAY indicate that a proper patientprescriber relationship does not exist such as:

- The prescriber routinely prescribes the same "cocktail" or combination of drugs for pain treatment to most or all of his/her patients, particularly where DEA and other authorities have identified the combination as potentially abused (e.g., oxycodone, alprazolam and carisoprodol or any combination of drugs from these three drug classes).
- 7. <u>Drugs Presented for Filling 45 Days Apart</u>: The DEA has pointed out that the drug purchase window for suspicious drug combinations may be as long as 45 days. As one CVS employee wrote:

Our DEA Consultant Tony Sheller would like to follow-up his Weds email with the following:

In the very little (and limited) data mining I have done to date, (if I did it right!) I have found instances where a patient is getting at least

2 of the cocktail drugs from the same pharmacy in the last 45 days. As I'm unable to see if that store is purchasing oxycodone, hydromorphone, etc is someone at CVS reviewing such situations if they exist. These are the kind of transactions that concern DEA.

## CVS-MDLT1-000078009.

8. Drugs Presented for Filling Within "12 plus" day Window: Walgreens's internal documents instruct that when certain components of drug combinations are presented by a patient for filling within "12 days plus" of each other, a red flag accrues.

Cocktails identified as an Opioid or Hydrocodone, Benzodiazepine and Soma, where the Benzodiazepine and Soma were dispensed within 12 days plus of the Opiate dispensing date.

## WAGMDL00054502 at 54512.

Cocktails = Where the Benzodiazepine and Carisoprodol (or Gabapentin) were both dispensed within 12 days plus of the Opiate dispensing date.

WAGMDL00674922 at speaker notes to slide 21.

Cocktails identified as an Opiate or Hydrocodone, Benzodiazepine and Carisoprodol, where the Benzodiazepine and Carisoprodel (or Gabapentin) were both dispensed within 12 days plus of the Opiate dispensing date.

WAGMDL00256710 at speaker notes to slide 11.

For more extensive discussion of the above authorities and more than fifty other citations, please see the attached spreadsheet.

Best regards,

/s/ Peter Mougey

Peter Mougey Levin Papantonio

/s/ Mark Pifko

Mark Pifko Baron & Budd

cc: Defendants' Counsel Plaintiffs' Counsel